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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,025	03/02/2004	Robert Frederick Veasey	02481.1836	9747
22852	7590	01/06/2010		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER PATEL, SHEFALI DILIP	
			ART UNIT	PAPER NUMBER
			3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,025

Applicant(s)

VEASEY ET AL.

Examiner

SHEFALI D. PATEL

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009 and 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 10 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 11-15, 17, 18 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Withdrawal of Finality of Last Office Action

1. Based on the decision to reopen prosecution by the Panel in the Pre-Appeal Brief Review, conducted on October 22, 2009, Applicant's request for reconsideration of the finality of the rejection of the last Office Action is persuasive, and therefore, the finality of that action is withdrawn.

Acknowledgments

2. Currently, claims 1-4, 7-9, 11-15, 17, 18, and 22 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 1 and 22, the claims invoke means-plus-function language, such as dose selecting means and dose expelling means; however, the specification does not clearly state the structures that are associated with the means-plus-function language. Therefore, it is unclear which structures correspond to these means-plus-function terms.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7-9, 11-15, 17, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs et al (US 6,221,046).

In regards to claim 1, Burroughs et al teaches a pen-type injector (Figures 1-15) comprising:

- a. a housing (housing [22])
- b. a cartridge (cartridge [40]) containing medicinal product, the cartridge being retained within the housing
- c. a dose selecting means (dial mechanism [34]) for selecting a dose of medicinal product to be expelled
- d. a dose expelling means (leadscrew [38], button [32], and nut [36]) for expelling the selected dose of medicinal product, wherein the housing comprises a unitary housing within which the dose selecting means and the dose expelling means are moveably retained and wherein the cartridge is enclosed within the housing together with the dose selecting means and the dose expelling means (Figure 1)

In regards to claims 2, 4, 7-9, 12, 13, 15, 17, and 18, Burroughs et al teaches a pen-type injector (Figures 1-15) comprising:

- a. a housing (housing [22])
- b. a piston rod (leadscrew [38]) having a screw thread
- c. an insert (ledges [178][180]) located in the housing [22] and through which the piston rod [38] may rotate
- d. ratchet means (tangs [182][184]) associated with the insert to ensure the piston rod [38] only rotates in a single direction through the insert
- e. a dose dial sleeve (dial mechanism [34]) rotatable with respect to the housing and the insert
- f. a drive sleeve (nut [36]) which is axially displaceable but not rotatable with respect to the piston rod
- g. a button (button [32]) located on the drive sleeve and rotatable with respect to the drive sleeve
- h. clutch means (engagement of splines [144] and teeth [192]) which upon depression of the button prevents rotation between the dose dial sleeve and the drive sleeve

In regards to claims 3 and 14, Burroughs et al teaches a nut (splines [144]) which is rotatable with respect to the drive sleeve [36] and axially displaceable but not rotatable with respect to the dose dial sleeve [34] (Figure 1).

In regards to claim 11, Burroughs et al teaches that an outer surface of the dose dial sleeve [34] includes graphics and wherein the housing [22] is provided with an aperture or

window (lens [25]) through which a portion of the graphics may be viewed (column 10, lines 5-14).

In regards to claim 22, Burroughs et al teaches a pen-type injector (Figures 1-15) comprising:

- a. a housing (housing [22])
- b. a cartridge (cartridge [40]) containing medicinal product, the cartridge being retained within the housing
- c. a piston rod (leadscrew [38])
- d. a dose selecting means (dial mechanism [34]) for selecting a dose of medicinal product to be expelled
- e. a dose expelling means (button [32] and nut [36]) for expelling the selected dose of medicinal product
- f. wherein the dose expelling means directly engages an end of the piston rod, and the housing comprises a unitary housing within which the dose selecting means and the dose expelling means are moveably retained (Figure 1)

Response to Arguments

7. Applicant's arguments with respect to claims 1-4, 7-9, 11-15, 17, 18, and 22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
1/2/2010

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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